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MAR 28 2006

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,034,239. The application was filed on September 7, 2005, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda at (571)272-7754 (telephone) or (571)273-7754 (facsimile).

Kery A. Fries

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Mark Chao, Ph.D., J.D.
Takeda Pharmaceutical Company, Limited
475 Half Day Road
Lincolnshire, IL 60069

RE: ROZEREM™ (ramelteon)
FDA Docket No. 2006E-0040